# Exhibit A

to PROPOSED SECOND CONSOLIDATED AMENDED COMPLAINT

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

BIOPURE CORPORATION, THOMAS MOORE, HOWARD RICHMAN, and JANE KOBER

Defendants.

Civil Action No.

**JURY TRIAL DEMANDED**

05 CA 11853 WGY

## COMPLAINT

Plaintiff Securities and Exchange Commission (the "Commission") alleges:

### Summary

1. In 2003, Biopure Corporation ("Biopure"), and its chief executive officer, head of regulatory affairs and general counsel engaged in a fraudulent scheme to misrepresent and conceal from investors the truth about its applications for Food and Drug Administration ("FDA") approval of Hemopure.

2. Hemopure is a biotechnology product that is designed to deliver oxygen to tissues as a substitute for red blood cells. To date, Hemopure has not been approved by the FDA for use in humans. Since its founding in 1984, defendant Biopure has devoted substantially all of its resources toward developing Hemopure for human use. In July 2002, Biopure submitted a biologics license application ("BLA") to the FDA for approval to use Hemopure for the treatment of acutely anemic patients undergoing orthopedic surgery. In March 2003, the company also applied for FDA approval to perform clinical trials of Hemopure on human trauma victims in hospitals.

3. In April 2003, Biopure began receiving negative information from the FDA. On or about April 9, 2003, the FDA imposed a clinical hold barring the company from conducting clinical trials of Hemopure on trauma victims because of "safety concerns" arising out of the FDA's preliminary assessment of Biopure's BLA. In or about May 2003, the FDA denied Biopure's request to lift the clinical hold. Then, on or about July 30, 2003, Biopure received two lengthy and detailed letters from the FDA. In one letter, the FDA again refused to allow the clinical trials because of "an unreasonable and significant risk of illness or injury" to human subjects. The other letter was the FDA's complete response letter to the BLA, in which the FDA informed Biopure that it was not approving Biopure's BLA at that time because of extensive and significant deficiencies in Biopure's application and because of concerns about the lack of safety and efficacy of Hemopure. Receipt of the complete response letter meant that the FDA had completed its review of the BLA and would have an additional six months to review a resubmission by the company, if and when the company addressed all deficiencies identified by the FDA. One year later, the company still had not addressed all deficiencies raised in the complete response letter and decided instead to shift its focus to developing Hemopure for a different application.

4. Throughout 2003, Biopure was also in need of additional capital to satisfy its continuing financial needs. Biopure had not been profitable at any point since its founding. Several times during 2003, as it had done previously and since, Biopure was seeking to raise money by accessing public and private capital markets through the sale of additional shares of stock.

5. For more than eight months from April 9 until December 24, 2003, Biopure concealed the clinical hold from investors while touting a potential use of Hemopure by trauma victims in multiple securities offerings, public filings, press releases and investor conference calls. Moreover, on August 1, 2003, two days after receiving the complete response letter from the FDA, Biopure issued a fraudulent and misleading press release that gave the false impression the company had received positive news from the FDA. That day, Biopure's stock closed at $7.30 per share, a 22% increase over its previous day close. For four additional months from August until December 11, 2003, Biopure continued to conceal from investors that it had received a complete response letter from the FDA, continued to make false statements about its dealings with the FDA and failed to disclose the true scope and nature of the deficiencies with the BLA identified by the FDA. Indeed, on one occasion in September 2003, Biopure disclosed in a prospectus filed with the Commission that the July 30 letter it received was a complete response letter. When Biopure's stock price dropped on heavy trading, the company told investors that the reference to the letter as a complete response letter was a "mistake" by a "junior lawyer at a law firm" retained by the company. The disclosure was quickly "fixed" with the filing of an amended prospectus that omitted the reference to the letter as a "complete response letter."

6. As the truth about Biopure's applications for FDA approval gradually became public, through a series of incomplete disclosures, the market reacted. As of year-end 2003, Biopure stock was trading below $3.00 per share.

7. By engaging in the scheme set forth in this Complaint, Biopure engaged in acts, practices and courses of business that constitute violations of Section 17(a) of the Securities Act

of 1933 ("Securities Act") and Sections 10(b) and 13(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rules 10b-5, 12b-20, 13a-11 and 13a-13 thereunder. Additionally, by engaging in the scheme set forth in this Complaint, each of individual defendants Moore, Richman, and Kober violated Section 17(a) of the Securities Act, Section 10(b) of the Exchange Act and Rule 10b-5 thereunder and aided and abetted Biopure's violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-11, 13a-13 thereunder, and defendant Moore further violated Rule 13a-14 of the Securities Act.

8. Unless restrained and enjoined, defendants will continue to engage in acts, practices, and courses of business as set forth in this Complaint or in acts, practices, and courses of business of similar object and purpose. Accordingly, the Commission seeks: (i) entry of a permanent injunction prohibiting each defendant from further violations of the relevant provisions of the federal securities laws; (ii) orders barring each of defendants Moore, Richman, and Kober from serving as an officer or director of a public company; (iii) the imposition of a civil monetary penalty in light of the egregious nature of defendants violations; and (iv) other equitable relief as the Court in its discretion deems just.

**Jurisdiction**

9. The Commission brings this action pursuant to Section 20 of the Securities Act [15 U.S.C. §§ 77t], and Sections 20(e) and 21(d) of the Exchange Act [15 U.S.C. §§ 78t(e) and 78u(d)].

10. This Court has jurisdiction over this action pursuant to Sections 20 and 22(a) of the Securities Act [15 U.S.C. §§ 77t and 77v(a)] and pursuant to Sections 21 and 27 of the Exchange Act [15 U.S.C. §§ 78u and 78aa]. Additionally, defendant Biopure's principal place of

business is in this District and many of the acts and practices set forth in this Complaint occurred in this District.

11. In connection with the conduct described in this Complaint, each of defendants directly and indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

**The Defendants**

12. **Biopure**, a Delaware corporation, is a biopharmaceutical company with headquarters in Cambridge, Massachusetts. Biopure's common stock is registered under Section 12(g) of the Exchange Act and trades on the NASDAQ Stock Exchange under the symbol "BPUR." Biopure has essentially one product, an oxygen therapeutic derived from bovine hemoglobin, which Biopure developed for use as a blood substitute. The form of the product intended for human use, called Hemopure, has not been approved by the FDA.

13. **Thomas Moore**, 54, served as President, Chief Executive Officer and a director of Biopure from July 2002 until the Board of Directors requested his resignation in February 2004. Prior to joining Biopure, defendant Moore held various positions at Proctor and Gamble Company from 1973-1996, including President of Global Healthcare. From 1996-2002, defendant Moore was President and Chief Executive officer of a medical communications and marketing company which provided consulting services to Biopure. Defendant Moore is a resident of Boston, Massachusetts.

14. **Howard Richman**, 53, was Biopure's Senior Vice President of Regulatory Affairs and Operations from spring 2003 until October 2003, when Biopure terminated his employment. He previously served as Biopure's Vice President of Regulatory Affairs and

Compliance from 2001 through the spring of 2003. Prior to joining Biopure, defendant Richman was a director of regulatory affairs at several biotech companies. Defendant Richman was a practicing doctor of podiatric medicine from 1978-1992. Defendant Richman is a resident of Houston, Texas.

15. **Jane Kober**, 62, is currently Senior Vice President, General Counsel, and Secretary of Biopure. Defendant Kober joined Biopure in May 1998, after serving as outside corporate counsel to the company from 1985-1986 and from 1990 until 1998. Defendant Kober is a resident of Bellport, New York.

## BACKGROUND

16. The FDA, an agency within the U.S. Department of Health and Human Services, is responsible for promoting the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner. Specifically, the FDA is responsible for protecting the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and the public health and safety are protected from electronic product radiation.

17. The Center for Biologics Evaluation and Research ("CBER") is a center within the FDA that regulates biologics, such as Hemopure, for human use. Biologics, which are also called biologic products or biological products, are products that generally are derived from living sources, in contrast to drugs, which generally are chemically synthesized.

18. Companies that manufacture biologics for introduction into interstate commerce are required to hold a license for the products. These licenses are issued by the FDA, through CBER. Licensing of biologics is similar to the new drug approval process for human drugs, and generally proceeds as follows: First, a manufacturer conducts initial laboratory and animal testing of the biologic, which does not require prior FDA approval. Next, a manufacturer submits an investigational new drug ("IND") application to the FDA for permission to conduct clinical trials in humans for a particular indication. Following clinical trials, the manufacturer will submit a biologics license application ("BLA") to the FDA for approval. The FDA's review of new BLAs, and for new indications for already approved products, requires evaluating the scientific and clinical data submitted by manufacturers to determine whether the product meets the FDA's standards for approval.

19. During the relevant period, the FDA's performance goals and procedures, adopted in connection with the Prescription Drug User Fee Act of 1992, as periodically reauthorized ("PDUFA"), provided that the FDA had ten months to review a BLA. The FDA was also entitled to a 90-day extension if an applicant were to submit a major amendment to its application during the final three months of the review period. Once the FDA completed its review of a BLA, if a product met the standards for approval, the FDA would approve the product for marketing. If the product did not meet the standards for approval, the FDA would issue a "complete response letter" (sometimes referred to as an "action letter") setting forth the deficiencies of the application.

20. After the FDA issues a complete response letter for a BLA, the applicant could make a further submission. For non-minor resubmissions, PDUFA performance goals and

procedures provided the agency with an additional six months to reply to the applicant's response, once the applicant had answered all questions and addressed all deficiencies set forth in the complete response letter.

**Hemopure and its Significance to Biopure**

21. Hemopure is Biopure's brand name for hemoglobin glutamer - 250 (bovine), an oxygen therapeutic derived from cow's blood that is designed to deliver oxygen to tissues as a substitute for red blood cells. Hemopure is one of only two products manufactured by Biopure. Oxyglobin, Biopure's other product, is an oxygen therapeutic created for veterinary use.

22. To date, the FDA has not approved the use of Hemopure in humans for any indication.

23. The development, approval by the FDA and ultimate success of Hemopure are highly material to Biopure. Since its inception in 1984, Biopure has devoted substantially all of its resources to the research, development and manufacturing of its oxygen therapeutic products. Although the company began generating revenue from the sale of Oxyglobin in 1998, Biopure has never been profitable. As of October 2002, the company had an accumulated deficit of more than $380 million. As of October 2003, the company's accumulated deficit had grown to more than $425 million.

24. Biopure's long-term prospects, even survival, are dependent upon receiving FDA approval for Hemopure. Biopure's short-term prospects during the relevant period depended also on obtaining the funding necessary to maintain the company's operations. As the company disclosed to investors in its Form 10-K filed with the Commission for fiscal year 2002, dated January 29, 2003, "[i]n order for us to remain a going concern we will require significant

funding."

**Biopure's Biologics License Application (BLA)**

25. On or about July 31, 2002, Biopure submitted a BLA to the FDA seeking approval to use Hemopure in the treatment of acutely anemic patients undergoing orthopedic surgery. For Hemopure to receive FDA approval for that indication, Biopure had to demonstrate that human clinical trials had established both the safety and efficacy of Hemopure. Under PDUFA goals and procedures, the FDA's target date for completing review of Biopure's BLA and sending the company either an approval letter or a complete response letter was at the end of May 2003.

26. In a letter to shareholders dated February 4, 2003, which was contained in Biopure's fiscal 2002 Annual Report, defendant Moore touted the filing of Biopure's BLA and described the company's priorities. The letter begins by declaring that Biopure "realized a tremendous achievement" by filing its BLA for use of Hemopure in an orthopedic surgery setting. Defendant Moore further stated that Biopure "anticipate[s] that the [FDA] will complete its review of our BLA by mid 2003." The letter described Biopure's "Business Strategy" with four bullet points. The first bullet referred to Biopure's BLA: "[s]uccessfully launch Hemopure under an orthopedic surgery indication in the United States." The second bullet referred to its trauma trials: "[c]linically develop Hemopure for trauma, ischemia, and adjunctive cancer therapy indications."

27. Under the heading, "Changing Gears for the Future," defendant Moore told investors that Biopure was developing Hemopure for use by trauma victims: "Our first clinical priority is to demonstrate the product's utility in stabilizing trauma patients in the emergency

room and pre-hospital, or ambulance, setting."

**Biopure Submits a Trauma IND and the FDA Imposes a Clinical Hold**

28. On or about March 7, 2003, Biopure ostensibly took a step toward achieving its "first clinical priority" by submitting an IND application to the FDA seeking permission to conduct clinical trials of Hemopure on human trauma victims in hospitals. In support of its submission, Biopure relied upon and referred the FDA to data from the pivotal clinical trial previously submitted in support of its pending BLA.

29. On or about April 9, 2003, members of the FDA staff telephoned defendant Richman, Biopure's primary contact with the FDA, to inform Biopure that the agency was imposing a clinical hold barring the company from initiating any clinical trials in connection with the trauma IND. The FDA staff stated that the clinical hold was imposed because of "safety concerns" arising out of data relating to the BLA clinical trials and because of "a preliminary assessment of the BLA." Specifically, the FDA staff expressly referred to data relating to serious adverse events suffered by participants in the BLA clinical trials, and stated that "the trial was on hold for safety and that in FDA's judgment it is unsafe to put this product in this patient population at this time."

30. Although he was not on the April 9 telephone call with the FDA, defendant Moore learned of the clinical hold by April 10, 2003, the next day. Defendant Kober was made aware, at least, that the FDA had questions about Biopure's trauma IND by early May and learned of the clinical hold no later than June 17, 2003.

**Biopure Begins Raising Money from Investors**
**Without Disclosing the Clinical Hold**

31. On or about April 16 and April 17, 2003, after learning of the clinical hold, Biopure filed with the Commission a Post-Effective Amendment No. 1 to a Form S-3 Registration Statement that had been filed in March 2003 and Rule 424(b)(3) prospectus supplements ("April Offering Documents") for the sale of up to 1,000,000 shares of common stock and warrants for the purchase of up to 500,000 shares of common stock. The April Offering Documents were signed by defendant Moore. Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the April Offering Documents, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

32. In the April Offering Documents, Biopure made the following statements, among others:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully . . . .
>
> * * *
>
> The Company expects to initiate additional pre-clinical and clinical trials this year to expand the indications for Hemopure beyond surgery.
>
> * * *

> We are also developing Hemopure for potential use in trauma and other medical applications.

33. Biopure's April Offering Documents were false and misleading because they misled investors about the true status of Biopure's clinical trials for the trauma indication. For example, although they discussed the potential use of Hemopure for trauma victims, the April Offering Documents misled investors by failing to disclose that the FDA had barred Biopure from conducting clinical trials on trauma victims for safety reasons. The April Offering Documents further misled investors by falsely stating that an indication involving Hemopure's perioperative use in orthopedic surgery was the "only" indication applied for, when, in truth, Biopure had also sought permission to conduct trials for the trauma indication. The April Offering Documents further misled investors by disclosing a future "expectation" to expand Hemopure's indications, design additional trials and submit them to the FDA for review, when, in truth, Biopure already had designed additional clinical trials, submitted the trial designs to the FDA for review, and received a clinical hold from the FDA. The April Offering Documents further misled investors by referring to development plans for the trauma indication without disclosing that the FDA placed the trauma indication on clinical hold for safety reasons arising out of the FDA's preliminary assessment of Biopure's BLA.

**The FDA Confirms the Clinical Hold in Writing and Informs Biopure of Serious Concerns Relating to its Pending BLA**

34. On or about April 25, 2003, the FDA sent Biopure a letter, addressed to defendant Richman, confirming that it had imposed a hold on clinical trials of the trauma IND because "subjects would be exposed to an unreasonable and significant risk of injury" ("April 25 Letter"). The April 25 Letter reiterated that the safety concerns that compelled the imposition of a clinical

hold arose out of a preliminary assessment of the company's BLA. The FDA stated that "results of a pivotal human trial, used in support of the Hemopure BLA, and referred to in the IND, indicated that use of Hemopure, compared to human blood was associated with a higher incidence of life-threatening SAEs [Serious Adverse Events], including death and cardiac arrest." Defendants Moore and Richman received a copy of the April 25 Letter by no later than April 30, 2003.

**Biopure Continues to Raise Money from Investors Without Disclosing the Clinical Hold or the FDA's Serious Concerns Relating to its Pending BLA**

35. On or about May 6, 2003, Biopure filed with the Commission a Rule 424(b)(3) prospectus supplement to the April Offering Documents, dated May 2, 2003, and a Rule 424(b)(3) prospectus supplement to the April Offering Documents, dated May 5, 2003 (collectively, the "May Prospectus Supplements"). The May Prospectus Supplements, in the aggregate, provided for the sale of up to 1,715,687 shares of common stock and warrants to purchase up to 343,138 shares of common stock. The May Prospectus Supplements incorporated by reference certain of Biopure prior public filings, including prior offering documents and periodic reports. Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the May Prospectus Supplements, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

36. Biopure's May Prospectus Supplements were false and misleading because they failed to disclose that the FDA had barred Biopure from conducting clinical trials of Hemopure on trauma victims for safety reasons arising out of a preliminary assessment of Biopure's BLA. The May Prospectus Supplements further misled investors by incorporating by reference the false

and misleading statements and omissions contained in the April Offering Documents.

**Biopure Unsuccessfully Petitions the FDA to Lift the Clinical Hold and Continues to Raise Money from Investors Without Disclosing the Clinical Hold or the FDA's Serious Concerns Relating to its Pending BLA**

37. On May 12, 2003, in response to the FDA's clinical hold, Biopure made an extensive submission to the FDA to request that the FDA lift its clinical hold. The submission, termed a "complete response" to the FDA's April 25 Letter, was signed by defendant Richman, defendants Moore and Richman participated in drafting and reviewing it, and defendant Kober was aware of the submission when it was made.

38. On or about May 14, 2003, Biopure filed a Form 8-K with the Commission ("May 14 Form 8-K"). Defendants Moore and Kober reviewed and approved the May 14 Form 8-K prior to its filing.

39. The May 14 Form 8-K attached as an exhibit a Standby Equity Distribution Agreement, dated April 16, 2003, between Biopure and BNY Capital Markets, Inc. ("CMI") pursuant to which Biopure could issue and sell up to $10,000,000 of shares of its class A common stock from time to time through CMI, as Biopure's exclusive agent for the offer and sale of the shares. Among the terms of the agreement that disclosed in the May 14 Form 8-K was Biopure's representation and warranty that the company's registrations statements and prospectuses:

> . . . conformed and will conform in all material respects to the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder, and none of such documents contained or will contain at such time an untrue statement of a material fact or omitted or will omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

40. The May 14 Form 8-K was false and misleading to investors because, as described herein, the April Offering Documents and May Prospectus Supplements contained untrue statements of material fact or omitted to state material facts necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

41. On May 22, 2003, Biopure issued a press release announcing its results for the second quarter of fiscal year 2003 ("May 22 Press Release") and included the text of the release in a Form 8-K filed with the Commission ("May 22 Form 8-K"). Defendants Moore, Richman, and Kober each substantially participated in drafting, reviewing and/or approving the May 22 Press Release.

42. The May 22 Press Release contained a section entitled, "Recent Corporate Events." Among the "Recent Corporate Events" listed was a statement referring to clinical trials for a trauma indication: "Biopure is preparing for a Phase 2a in-hospital trauma trial."

43. The May 22 Press Release was misleading to investors because, among other things, although the May 22 Press Release described planned clinical trials for a trauma indication, Biopure concealed the truth from investors, that the FDA had placed the in-hospital trauma trial on clinical hold due to safety concerns arising out of its preliminary assessment of the BLA.

44. That same day, May 22, 2003, defendants Moore and Richman participated in a conference call with analysts and investors regarding the earnings release for the second quarter ("May 22 Investor Call"). During the May 22 Investor Call, defendant Moore stated, among other things:

> [W]e continue to be very hopeful of an [FDA] response on our [biologics] license application by mid-year or sooner, and we continue to not be aware of any major issues with that application at this time.
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> * * *
>
> Our aim will be to have the product, again, assuming we get approved, on or about June 1st to the end business [sic] and moving product no later than October 1st.
>
> * * *
>
> Parkman Hospital is going to be our initial clinical center to conduct the already announced in-hospital trauma trials that will set us up for subsequent pre-Hospital trials to establish an additional trauma indication for Hemopure.

45. The May 22 Investor Call was false and misleading because defendants Moore and Richman misled investors about the true information the company had received from the FDA. For example, the statement that "we continue to not be aware of any major issues with that application at this time" was false and misleading because the FDA had already informed defendants of serious concerns about data from the pivotal BLA clinical trial, which necessitated imposing a bar on clinical trials on trauma victims for safety reasons. Moreover, the clinical hold was imposed based on the FDA's preliminary assessment of the BLA. In addition, the reference to a particular hospital as Biopure's "initial clinical center to conduct the already announced in-hospital trauma trials" misled investors because defendants failed to disclose that the clinical hold barred Biopure from initiating the "already announced in-hospital trauma trials." The May 22 Investor Call was further misleading because although defendants touted the potential use of Hemopure for trauma victims, they failed to disclose that the FDA had barred Biopure from conducting clinical trials on trauma victims for safety reasons based on the FDA's preliminary

assessment of the BLA.

**Biopure's Submission Fails to Persuade the FDA to Lift the Clinical Hold**

46. On or about May 30, 2003, the FDA sent two letters to Biopure, addressed to defendant Richman, in response to Biopure's May 12 request to lift the clinical hold. In one May 30 letter, the FDA informed Biopure that the clinical hold would not be lifted. The FDA stated that Biopure's request contained serious inconsistencies and failed to address the FDA's safety concerns. In addition, the FDA informed Biopure that its "conclusions about product safety remain unchanged," and the FDA required the company to conduct "at least three additional studies in conscious swine" to address particular concerns prior to any testing in humans.

47. In the other May 30 letter to Biopure, the FDA informed Biopure that it was extending the deadline to complete its review of Biopure's BLA for 90 days, until August 29, 2003. The FDA expressly stated that the extension was taken because information submitted by Biopure in its May 12 request to lift the clinical hold on the trauma indication contained significant new analyses of the BLA clinical data and therefore was a "major amendment" to Biopure's BLA.

48. Defendants Moore and Richman received copies of both May 30 letters on or about May 30, 2003, and defendant Kober received a copy of, at least, the May 30 letter extending the deadline for the FDA to complete its review of the BLA on or about May 30, 2003.

**Biopure Discloses False Reasons for the 90-day Extension and Misleadingly Characterizes the Extension as Positive News for the Company**

49. On May 30, 2003, after receiving both May 30 letters from the FDA, Biopure issued a press release ("May 30 Press Release") and held a conference call with investors and

analysts ("May 30 Investor Call"). Defendants Moore, Richman, and Kober each substantially participated in drafting, reviewing and/or approving the May 30 Press Release.

50. The May 30 Press Release stated, among other things, that:

> Biopure submitted its BLA on July 31, 2002. Under FDA performance goals . . ., the agency has up to 10 months from the submission date to review and act on the BLA, making the original action due date June 1, 2003. As part of the normal review process, Biopure has responded to FDA questions regarding the application. The agency has classified the latest responses submitted in mid-May 2003 as additional analyses of previously submitted data, which under FDA standard operating procedures automatically provides the agency up to three months beyond the original action due date to review the data.

51. Biopure's May 30 Press Release was false and misleading because it misled investors about the true information the company had received from the FDA. For example, the May 30 Press Release falsely stated that Biopure had responded to FDA questions regarding the BLA, when, in truth, the company had responded to questions relating to the trauma IND and the clinical hold, which the company had never disclosed. The May 30 Press Release further falsely stated that Biopure's submission was "part of the normal review process" of the BLA and was Biopure's "latest responses" to FDA questions on the BLA, when, in truth, the submission was the company's complete response to the FDA's April 25 clinical hold letter and was expressly made in an effort to persuade the FDA to lift the clinical hold.

52. In addition, the May 30 Press Release failed to disclose, among other things, that the 90-day extension resulted from Biopure's request to lift the clinical hold. The May 30 Press Release failed to disclose that the FDA had placed the trauma IND on clinical hold. The May 30 Press Release further failed to disclose that the FDA had refused to lift the clinical hold even after Biopure had made a substantial submission to the agency. The May 30 Press Release

further failed to disclose that the clinical hold was imposed based on the FDA's concerns about the safety of Hemopure arising out of the same data that was submitted in support of the BLA.

53. Later that same day, defendants Moore and Richman participated in the May 30 Investor Call with investors and analysts. During the May 30 Investor Call, defendant Moore stated, among other things:

> We view this notification [of the 90-day extension] as a very positive development for Hemopure. First of all, we have a date which the agency has indicated their intent to give us an action letter. Second, it confirms what we already knew, that is, that the agency has devoted considerable effort to this application. And third, as we also already knew, that now our investor community knows, there is nothing in our application which is warranted a denial of that application at the three key decision points we've passed so far in the PDUFA process. By that, I mean our BLA was accepted, it was also continued through the mid-cycle review conducted by the agency, and now, at the PDUFA guideline date for a first response, we've not had a denial, but rather a going forward to additional consideration. The added time we're going to get over the next three months will not only allow us to insure we can fully answer any additional questions the FDA might choose to send our way, but also allow us to complete legal negotiations and to continue forward with the commercial preparations we are making against a hopeful approval on August 29th for the name of introducing this product on or about the October introductory guideline we mentioned in our conference call last week. So we feel very positive about this . . . .

54. Also during the May 30 Investor Call, defendants Moore and Richman engaged in colloquies with stock analysts who participated in the call:

Analyst 1: [D]id the FDA request any additional data to be submitted, or why do you think that basically the FDA extended the timeline for the review process?

Moore: The FDA did not request any additional data . . . .

Richman: . . . This is what normally happens with any submission. As Tom has told the public over the past many months, is that we are in continued dialogue with the agency and during that period of time, they have requested information which we have sent back to them. It's a normal process with any application. Be that as it

may, the agency, during the course of reviewing the information has the opportunity to take additional time to allow them to give a complete and additional thorough review of all information to make a thorough conclusion on application. This type of response from the FDA is very common with biologic licensing applications. Most recently, in 2001 and 2002, of the 11 BLAs that were submitted to the Food and Drug Administration, all 11 of them went on to the extended period of time for review which was outside the normal PDUFA 10 months. It is within the PDUFA guidelines to allow them to do that and they still meet their matrix for approval for their guidance acumen.

* * *

Analyst 2: . . . I guess I'm a little bit confused on the timing of the submission of whatever it is you did submit to the FDA given that your original BLA was submitted in July 31st of last year. I guess my question is why are you still having to provide information to the FDA? You said mid-May there was a resubmission of some sort. Why nine and a half months after the original BLA was submitted are you still having to provide information?

Moore: It's actually . . . it's a continual process of providing information. I'm going to let Howard comment on this specifically, but it would be difficult to categorize how many hundreds of questions we've answered in the review of this BLA to date. This mid-May submission was some additional analysis which we provided on data that was already in the BLA. At the time, we didn't consider it a major amendment to the BLA but the FDA looked at that as a reason to extend it. But I'll let Howard comment on that.

Richman: . . . Just as a point of clarification this is a normal occurrence. I've been lucky to be involved with 12 other approval processes outside of Biopure and this is a normal thing that happens. We're, in fact, in constant contact with the agency when they're requesting information in real time. So this is not anything new that can happen. And what we have done is supply responses back to their continual questions to allow them, again, as I mentioned earlier, to give complete and thorough response to this first in class application.

Analyst 2: I understand there was a continuing dialogue and questions and answers, but it would seem that for there to be some sort of submission that would extend the PDUFA date another two months, it would have to be something material. And I guess I'm just surprised that nothing was disclosed in mid-May when this additional submission was made.

Moore: To be clear, we were simply responding to a new set of questions from FDA. It did not involve any new data. And so frankly, it was well within the range of

other questions we've answered in the past. When we made that response, we didn't characterize it as a major amendment to the BLA. I think the FDA chose to do that and I think that really, how do I phrase this diplomatically, I think that's a way for them to get this additional consideration time as opposed to some startling new insight on the application. But that's not my role to call I would say, as Howard has already said, so far the FDA's extended on 11 straight BLAs, so we're number 12.

* * *

Analyst 3: . . . Could you please be a little more specific in terms of -- the company has submitted additional analyses of previously submitted data. Could you be a little more specific as to what elements of the clinical data that that refers to?

Moore: I can't be a lot more specific.

Analyst 3: I mean, is it safety, is it statistical procedure, is it some auditing of patient records? I mean, could you just be somewhat more specific?

Moore: Well, all patient records have been audited and so all that's been done, so that's not at issue as far as I know anyway.

Analyst 3: Or merely is it formatting or you know?

Moore: It's actually - - it was a dialogue really about how to look at the clinical data. As you know, there are various analyses used to look at our efficacy and safety data and we just had a dialogue about the different ways you could look at the analyses that are performed on the data. And that's really as far as I want to characterize it.

Analyst 3: But could you just give us maybe a broader ballpark sense as to - - you know, just a broad area that it is -- is there a specific area that it's in that's a broad area that maybe you could characterize it? That's more specific than just it's the clinical data?

Moore: Well, I mean, all the clinical data has to do with safety and efficacy. That's the only thing in measure in these clinicals. And so, the dialogue is over those clinical and safety and efficacy data. And again, we have answered some questions on a pretty broad basis. When I talk about it as how to look at the clinical analysis, it's exactly what it was. So I think that's as far and as specific as I really want to be at this point.

55. The May 30 Investor Call was false and misleading because defendants Moore

and Richman misled investors about the true information that the company had received from the FDA. For example, defendants misled investors by falsely characterizing the 90-day extension as merely part of a normal, continuing dialogue with the FDA about the pending BLA, when, in truth, it arose out of Biopure's submission to lift the clinical hold on the trauma IND. In addition, defendants' optimistic statements about the 90-day extension misled investors because they were contrary to the express reasons for the extension given by the FDA staff. In answering direct questions from analysts, defendants further misled investors by providing false information about the true reason for the 90-day extension. Defendants further failed to disclose that the FDA had placed the trauma IND on clinical hold due to safety concerns and that the clinical hold was imposed based on the FDA's preliminary assessment of the BLA.

**Biopure Continues to Conceal the Clinical Hold from Investors in Periodic Reports and Offering Documents Filed with the Commission**

56. On or about June 16, 2003, Biopure filed with the Commission a Form 10-Q quarterly report for the quarter ended April 30, 2003 ("June 16 Form 10-Q"). The June 16 Form 10-Q was signed by defendant Moore, who certified that it did not "contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the non-financial reporting sections of the June 16 Form 10-Q, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

57. On or about June 19, 2003, Biopure filed a Form S-3 registration statement and prospectus with the Commission and on or about July 2, 2003, Biopure filed a Pre-Effective

Amendment No. 1 for Form S-3 registration statement and prospectus with the Commission for the sale of common stock and warrants for the purchase of common stock (collectively, the "Summer 2003 Shelf Registration"). On or about July 3, 2003, Biopure filed a Rule 424(b)(3) prospectus with the Commission for the sale of common stock and warrants for the purchase of common stock ("July 3 Prospectus").

58. Defendant Moore signed the Summer 2003 Shelf Registration. Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the Summer 2003 Shelf Registration and July 3 Prospectus, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

59. In each of the June 16 Form 10-Q, Summer 2003 Shelf Registration, and July 3 Prospectus, Biopure made the following statements, among others:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully . . . .

60. Biopure's June 16 Form 10-Q, Summer 2003 Shelf Registration, and July 3 Prospectus were false and misleading because they misled investors about the true status of Biopure's clinical trials for the trauma indication. For example, the June 16 Form 10-Q, Summer 2003 Shelf Registration, and July 3 Prospectus misled investors by failing to disclose that the FDA had barred Biopure from conducting clinical trials of Hemopure on trauma victims for

safety reasons. The June 16 Form 10-Q, Summer 2003 Shelf Registration, and July 3 Prospectus further misled investors by falsely stating that an indication involving Hemopure's perioperative use in orthopedic surgery was the "only" indication applied for, when, in truth, Biopure had also sought permission to conduct trials for the trauma indication. The June 16 Form 10-Q, Summer 2003 Shelf Registration, and July 3 Prospectus further misled investors by disclosing a future "expectation" to expand Hemopure's indications, design additional trials and submit them to the FDA for review, when, in truth, Biopure already had designed additional clinical trials, submitted the trial designs to the FDA for review, and received a clinical hold from the FDA.

**Biopure Again Unsuccessfully Petitions the FDA to Lift the Clinical Hold and Continues to Raise Money from Investors Without Disclosing the Clinical Hold or the FDA's Serious Concerns Relating to its Pending BLA**

61. On or about July 2, 2003, Biopure made a submission to the FDA in response to the FDA's May 30 letters in a further attempt to have the clinical hold lifted. Defendant Richman prepared and signed this submission at defendant Moore's direction, and defendant Moore received and reviewed it prior to submission to the FDA.

62. On or about July 17, 2003, Biopure filed a Form 8-K with the Commission ("July 17 Form 8-K"). Defendants Moore and Kober reviewed and approved the July 17 Form 8-K prior to its filing.

63. The July 17 Form 8-K attached as an exhibit a Placement Agency Agreement, dated July 17, 2003, between Biopure and ThinkEquity Partners, LLC pursuant to which ThinkEquity Partners, LLC would act as exclusive placement agent for Biopure for the sale by Biopure of up to $17,250,000 of shares of its class A common stock. Among the terms of the agreement that was disclosed in the July 17 Form 8-K was Biopure's representation and warranty

that the company's registrations statements and prospectuses:

> . . . conformed and will conform in all material respects to the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder, and none of such documents contained or will contain at such time an untrue statement of a material fact or omitted or will omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

64. The July 17 Form 8-K was false and misleading to investors because, among other things, the company's prior filings with the Commission contained untrue statements of material fact or omitted to state material facts necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

65. On or about July 18, 2003, Biopure filed a Rule 424(b)(5) prospectus supplement to the July 3 Prospectus for the sale of up to 3,083,000 shares of common stock to institutional investors ("July 18 Offering Document"). The July 18 Offering Document incorporated by reference certain of Biopure prior public filings, including prior offering documents and periodic reports. Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the July 18 Offering Document, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

66. Biopure's July 18 Offering Document was false and misleading because, among other things, it failed to disclose that the FDA had barred Biopure from conducting clinical trials of Hemopure on trauma victims for safety reasons. The July 18 Offering Document further misled investors by incorporating by reference prior public filings, discussed herein, that contained false statements and omissions regarding the clinical hold imposed by the FDA based on safety concerns arising from a preliminary assessment of Biopure's BLA.

**The FDA Declines to Approve Hemopure, Issues a**
**Complete Response Letter to the BLA and Refuses to Lift The Clinical Hold**

67. On July 30, 2003, Biopure received two letters from the FDA: a complete response letter in which the FDA informed Biopure that its BLA was not approved, and a letter in which the FDA again declined to lift the clinical hold on the trauma IND.

68. From July 30, 2003 until December 11, 2003, in multiple public filings, press releases and statements, defendants misled investors by failing to disclose that they had received a complete response letter from the FDA, despite the fact that others, including FDA staff and Biopure's own outside regulatory counsel, repeatedly and consistently identified the letter to defendants as a complete response letter. From July 30 until December 11, defendants further misled investors in multiple public filings, press releases and statements by misrepresenting the nature and scope of the deficiencies in the BLA raised by the FDA and by failing to disclose the continuing clinical hold on the trauma indication.

69. The July 30 complete response letter began by stating that:

> The Center for Biologics Evaluation and Research (CBER) has completed the review of all submissions made relating to your Biologics License Application. Our review finds that the information and data submitted are inadequate for final approval action at this time based on the deficiencies outlined below.

70. The July 30 complete response letter also summarized the deficiencies of Biopure's BLA in 34 single-spaced pages. In total, the letter contained more than 220 deficiencies and questions regarding Biopure's clinical trials, its data and the safety and efficacy of Hemopure. Chief among these were questions about the conduct of Biopure's clinical trials and the integrity of its data, in particular whether controls were sufficient to ensure that the data

in Biopure's BLA submission was accurate and reliable enough to form the basis for conclusions about safety and efficacy, and about why Biopure failed to perform certain analyses as the FDA had expected and recommended. The FDA further expressly reserved its right to re-evaluate safety and efficacy data pending resolution, if possible, of data integrity issues. The complete response letter stated that the review clock was suspended with its issuance.

71. In the FDA's other July 30 letter, the FDA again refused to lift the clinical hold on the trauma IND "because human subjects are or would be exposed to an unreasonable and significant risk of illness or injury." In support of that conclusion, the FDA cited many of the same deficiencies and questions raised in its complete response letter to Biopure's BLA. As in the complete response letter, the clinical hold letter also questioned the controls of the clinical trials and the analysis of the resulting data, and raised concerns about the safety of Hemopure.

72. Defendants Moore, Richman, and Kober each received a copy of the July 30 complete response letter on or about July 30, 2003. Defendants Moore and Richman received copies of the July 30 clinical hold letter on or about July 30, 2003, and defendant Kober was made aware of the letter and its contents in discussions with other Biopure management no later than July 31, 2003.

73. Given the length, detail and substance of the deficiencies identified by the FDA, the July 30 complete response letter and the July 30 clinical hold letter were a major setback in Biopure's effort to gain FDA approval for Hemopure. This was especially so because as of July 30, 2003, Biopure had made two substantial submissions to the FDA seeking to lift the clinical hold, but had been unable to adequately address the FDA's concerns.

74. On or about the morning of July 31, 2003, defendant Richman telephoned a member of the FDA staff working on Biopure's BLA and trauma IND applications to discuss Biopure's next step after receipt of the complete response letter. The FDA staff member identified the letter as a complete response letter and told defendant Richman that within 10 days of its receipt, Biopure should take one of the following actions: amend the application; notify the FDA of its intent to amend the application; withdraw the application; or request a hearing. Defendant Richman asked whether because the complete response letter was issued 30 days before the due date, if Biopure were able to respond to the complete response letter within the 30 days, would it receive approval. The FDA staff member responded that with the issuance of a complete response letter, the review clock had stopped and no further review would be considered until Biopure responded to all deficiencies listed in the letter. The FDA staff member further told defendant Richman that a partial response would not be considered for review, a response to all listed deficiencies was required in order to re-start the clock. The FDA staff member further told defendant Richman that once the FDA received Biopure's response to the complete response letter, the agency gets a new review cycle of six months to review those responses.

75. On or about July 31, 2003, Biopure, acting through defendant Kober, contacted outside counsel that specialized in FDA regulatory matters concerning the complete response letter and a draft of a press release that the company intended to issue. The draft press release stated that Biopure had received a letter from the FDA, but did not identify it as a complete response letter. Biopure's outside counsel orally advised defendant Kober that he "didn't have time to read letter but looked like complete response." Outside counsel further advised

defendant Kober that a draft release disclosing receipt of the letter looked "unduly optimistic." Outside counsel further advised defendant Kober that issuance of the letter "30 days early in this context while true isn't great cause optimism [sic]." Defendant Kober informed defendants Moore and Richman of the substance of outside counsel's comments.

**Biopure Misleads Investors About the July 30 Letters**

76. On August 1, 2003, Biopure issued a press release ("August 1 Press Release") and included the text of the release in a Form 8-K filed with the Commission ("August 1 Form 8-K"). Defendants Moore, Richman, and Kober each substantially participated in drafting, reviewing and/or approving the August 1 Press Release.

77. The August 1 Press Release stated, among other things:

> Biopure Corporation (Nasdaq: BPUR) announced today that the U.S. Food and Drug Administration (FDA) has completed its review of the company's biologic license application (BLA) for Hemopure(R) [hemoglobin glutamer - 250 (bovine)] and issued a letter requesting additional information. The letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling. It does not request additional clinical trials. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.
>
> With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response.
>
> "We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining thirty days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible," said Biopure President and CEO Thomas A. Moore. "We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

78. After the August 1 Press Release was issued on the morning of August 1, 2003, Biopure's stock price rose 22.27%, from a closing price of $5.97 on July 31, 2003 to a closing price of $7.30 on August 1, 2003.

79. Biopure's August 1 Press Release was false and misleading because it misled investors about the true information that the company had received from the FDA. For example, the August 1 Press Release failed to disclose that Biopure had received a complete response letter from the FDA. In addition, the August 1 Press Release was misleadingly optimistic despite the fact that Biopure had received two detailed letters from the FDA that constituted a major setback in its effort to gain FDA approval for Hemopure. Defendants Moore's statement in the August 1 Press Release that the FDA was "encouraging" Biopure to "complete the approval process as quickly as possible" further misled investors because it had no basis in fact and was inconsistent with the seriousness and number of deficiencies identified by the FDA and the amount of time it would take Biopure to respond. References in the August 1 Press Release to 30 days remaining in the review cycle further misled investors about the amount of time that the FDA would have to respond -- six months -- once Biopure responded to all deficiencies in the letter. The August 1 Press Release further misled investors by stating that the FDA had not requested additional clinical trials when, in truth, the FDA was questioning the integrity of Biopure's data, a preliminary step prior to determination of whether new trials would be necessary and was further refusing to lift the hold barring clinical trials on trauma victims. The August 1 Press Release further failed to disclose anything about the clinical hold, including that the FDA had imposed one, that Biopure had received a lengthy and detailed letter refusing to lift the clinical hold which identified many of the same deficiencies and raised many of the same questions as the complete

response letter, or that Biopure had twice unsuccessfully attempted to persuade the FDA to lift the clinical hold.

80. On or about August 5, 2003, defendant Kober sent an e-mail to outside counsel specializing in FDA regulatory matter to request assistance with developing a strategy for responding to the FDA's complete response letter. In a response sent that same day, Biopure's outside counsel sent an e-mail to defendant Kober that identified the July 30 letter as a complete response letter.

**Biopure Continues To Misrepresent the Complete Response Letter and To Conceal the Existence of the Clinical Hold**

81. On August 21, 2003, Biopure issued a press release announcing its financial results for the 3rd quarter of fiscal year 2003 ("August 21 Press Release") and included the text of the press release in a Form 8-K filed with the Commission, dated September 15, 2003 ("September 15 Form 8-K"). Defendants Moore, Richman, and Kober each participated in drafting, reviewing and/or approving the August 21 Press Release.

82. The August 21 Press Release stated, among other things:

> On July 30th, the FDA sent Biopure a letter stating that the agency has completed its review of the company's BLA to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials. Biopure is preparing its response, which, when submitted, will restart the review clock.

83. Biopure's August 21 Press Release was false and misleading because it misled investors about the true information that the company had received from the FDA. For example,

the August 21 Press Release failed to disclose that Biopure had received a complete response letter from the FDA. References in the August 21 Press Release to 30 days remaining in the review cycle further misled investors about the amount of time that the FDA would have to respond -- six months -- once Biopure responded to all deficiencies in the letter. The August 21 Press Release further misled investors by stating that the FDA had not requested additional clinical trials when, in truth, the FDA was questioning the integrity of Biopure's data, a preliminary step prior to determination of whether new trials would be necessary and was further refusing to lift the hold barring clinical trials on trauma victims. The August 21 Press Release further failed to disclose anything about the clinical hold, including that the FDA had imposed one, that Biopure had received a lengthy and detailed letter refusing to lift the clinical hold which identified many of the same deficiencies and raised many of the same questions as the complete response letter, or that Biopure had twice unsuccessfully attempted to persuade the FDA to lift the clinical hold.

84. That same day, August 21, 2003, defendants Moore and Richman participated in a conference call with investors and analysts ("August 21 Investor Call"). During the August 21 Investor Call, defendant Moore stated, among other things:

> The agency has done us a big favor by providing what amounts to a complete detailed response and set of questions to Biopure prior to the end of the review cycle, and then stopping the review clock with 30 days remaining in the PDUFA cycle. They have thereby made a commitment to give us an action letter 30 days after we provide our response to their questions. They could just as easily have announced an end to the review cycle with their response, in which case they would have had two to six months to respond to our answers instead of the 30 day period.
>
> * * *

Our efforts to date suggest that we're in good shape so far to be able to answer FDA's questions.

85. During the August 21 Investor Call, defendants Moore and Richman engaged in colloquies with a stock analyst who participated in the call:

Analyst 1: . . . A couple of questions on the letter from the FDA. You used the term complete response a couple of times. But, this isn't a complete response letter. What is it exactly?

Moore: It's, and I'll ask Howard Richman to comment on this in just a second. It is -- I think Howard will call it a hybrid, and by that I mean it genuinely represents all the questions that FDA would like to have us answer, and so in that sense it's like a complete response. But normally a complete response letter brings an end to the review cycle. And the agency has elected not to do that, offering us this precious opportunity to get a response 30 days after we submit the answers to those questions. And so, that's what it is.

Analyst 1: It sounds like the response is going to take some time. Can you tell me about how many questions are involved? And the followup question is, depending on the length of your response, is it reasonable to expect that the FDA is going to be able to respond back within that 30 day timeline? If you give them a very exhaustive detailed response back, as I know you will, isn't it going to take the FDA longer than 30 days to respond back?

Moore: I think that's a very fair question, and that's one of the motivations we have for having a meeting with FDA simply so we can agree on how we're going to order this data and maybe how we can share some of the data as we go so that it makes it easier for them to meet that guideline.

Richman: I'll share this with yourself and for the other people listening. This type of letter is very unique. As Tom clearly stated for everyone, it is a hybrid, it's something that was done from the (indiscernible) perspective to work with Biopure in this aspect because you're right in stating that people have (indiscernible), this does not follow the area that we've seen where you look on FDA sites or in other complete responses. This was done with the specific intent to work with us. With that being said, it counts in such a way that they want us to be able to get back to them vis-a-vis this meeting and in our answers. Many of our answers will not be that detailed in response, some are in clarification, which will only meet the FDA with some points we're going to discuss with them. Other ones will just provide them information they requested in terms of clarification and follow-up source documents and other information they've asked about. So, when you say about a

detailed (indiscernible) response, in many ways it will not be. But it's also clear that the format that they have for us with FDA which will be clarified on a meeting in September will clearly enlighten us and them and give a clear pathway to the response in a correct time frame.

* * *

Analyst 2: . . . My question is, what will you do if Biopure doesn't get FDA approval?

Moore: . . . While we are continuing to be cautiously optimistic, we're on the approval track. If you ask us to specifically address this question, which you have, I guess what I'd say is the FDA doesn't really just say no. At least not in a situation like this where an application has been accepted and taken this far down the review track. What the FDA says is here's what you've got to do, guys, if you want to persuade us to say yes. And generally what they'd say is you need more information. I'm going to take a big leap here, Howard [Richman] may hit me. But if the information we've given them so far led them to say we can't approve it then they would've already said we can't approve it. Okay? You don't go back and forth like this because the product is not approvable. The question for the agency is the process of putting together the adequacy of the total data set.

* * *

Analyst 3: Is there anything on the work the trials that the military is doing in trauma yet?

Moore: We've not initiated human clinical trials in trauma with the military or for that matter on the civilian side as yet. So, we hope to get started on that ASAP. I think probably those trials will begin, however, at least after we have -- no sooner than after we filed our responses with FDA on the BLA questions. As I mentioned earlier in my flurry of discussions about meetings, Naval medical research has been very active in doing preclinical work on trauma with our product, and then sharing those results in several different forms actually. So, work is going on very actively on the trauma side, but I don't believe human trials will begin until after we have completed our answers to the BLA. Part of this is related to the fact that we already are engaged in FDA in a dialogue on a total clinical development program in trauma with FDA. And so we expect the final discussion on that with FDA will ensue after we've addressed the questions they've asked for us on the use in anemia from surgery indication.

86. Biopure's August 21 Investor Call was false and misleading because defendants misled investors about the true information that the company had received from the FDA. For

example, defendants misled investors by falsely characterizing the July 30 letter as a "hybrid" letter, when, in truth, it was a "complete response letter," and that fact had been confirmed by the FDA to defendant Richman at least two times by August 21, 2003. Defendants further misled investors by falsely stating that the FDA would have 30 days to review a submission from Biopure, when, in truth, the agency would have six months to review a submission once Biopure had addressed all deficiencies in the complete response letter. Defendant Moore's statements that the FDA did a "big favor" for Biopure and had "made a commitment to give us an action letter 30 days after we provide our response to their questions" further misled investors because, among other things, these statements had no basis in fact, were inconsistent with statements made by the FDA to Biopure and were contrary to the six month period the FDA would have to review a resubmission. Defendants further misled investors by stating that the company was "in good shape" to address the deficiencies and questions in the complete response letter, when, in truth, the deficiencies and questions were of such a substantial nature that Biopure would not be able to respond to them for years. Defendants further misled investors in the August 21 Investor Call by making optimistic statements about the likelihood of FDA approval, when, in truth, the deficiencies and questions in the two July 30 letters from the FDA, as well as concerns discussed by the FDA during telephone calls, were major obstacles to obtaining FDA approval. Defendants further misled investors during the August 21 Investor Call by discussing clinical trials of a trauma indication but concealing from investors that the FDA had barred Biopure from conducting clinical trials on trauma victims for safety reasons.

87. On or about August 22, 2003, Biopure filed a Form S-3 registration statement and prospectus with the Commission for the sale of common stock and warrants for the purchase of

common stock by selling security holders ("August Secondary Offering Documents"). Defendant Moore signed the August Secondary Offering Documents. Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the August Secondary Offering Documents, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

88. In the August Secondary Offering Documents, Biopure did not state that the July 30 letter it had received from the FDA was a complete response letter. In addition, Biopure made the following statement, among others:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully . . . .

89. Biopure's August Secondary Offering Documents were false and misleading because they misled investors about the true information that the company had received from the FDA. For example, Biopure's August Secondary Offering Documents failed to disclose, among other things, that the July 30 letter from the FDA was a complete response letter. The August Secondary Offering Documents further misled investors by failing to disclose that the FDA had barred Biopure from conducting clinical trials of Hemopure on trauma victims for safety reasons and that Biopure had twice unsuccessfully petitioned the FDA to lift the hold. The August Secondary Offering Documents further misled investors by falsely stating that an indication

involving Hemopure's perioperative use in orthopedic surgery was the "only" indication applied for, when, in truth, Biopure had also sought permission to conduct trials for the trauma indication. The August Secondary Offering Documents further misled investors by disclosing a future "expectation" to expand Hemopure's indications, design additional trials and submit them to the FDA for review, when, in truth, Biopure already had designed additional clinical trials, submitted the trial designs to the FDA for review, and received a clinical hold from the FDA.

**Biopure's Outside Counsel Confirms the July 30 Letter was a Complete Response Letter and a Six Month Review Period Would Apply to a Resubmission**

90. On or about August 26, 2003, acting at the request of Biopure management, Biopure's outside counsel contacted FDA staff to determine whether the FDA planned to issue a second response letter by August 29. Following that conversation, Biopure's outside counsel informed defendants Moore, Richman and Kober in e-mails and discussions that despite the use of some non-standard language and the issuance of the letter 30 days prior to the due date, the July 30 letter that Biopure received was a complete response letter for the BLA. Biopure's outside counsel further confirmed to defendants Moore, Richman and Kober that the review cycle had been completed without approval by the FDA and that the FDA would have six months to review any resubmission from Biopure.

**Biopure Continues To Misrepresent the Complete Response Letter and To Conceal the Existence of the Clinical Hold While Raising Money from Investors, Making Public Statements and Filing Periodic Reports with the Commission**

91. On September 12, 2003, Biopure filed a Form 424(b)(3) prospectus ("September 12 Prospectus") with the Commission. In the "Risk Factors" section of the September 12 Prospectus, Biopure stated that the July 30 FDA letter was a complete response letter.

92. On September 15, 2003, the following trading day, Biopure's stock price dropped by 6.5% on heavy trading. When asked about this trading activity, Biopure's Director of Corporate Communications attributed the stock movement to the disclosure that Biopure had received a complete response letter. In e-mail messages to investors, the Director of Corporate Communications stated that the reference to the letter as a "complete response letter" had been a "mistake" by a "junior lawyer at a law firm" used by the company.

93. On September 15, 2003, Biopure filed an amended Form 424(b)(3) prospectus ("September 15 Prospectus") with the Commission. The September 15 Prospectus omitted the reference to the July 30 letter as a "complete response letter." Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving the September 15 Prospectus, and defendant Richman reviewed disclosures regarding the regulatory status of Biopure's FDA submissions.

94. Also on or about September 15, 2003, Biopure filed with the Commission a Form 10-Q quarterly report for the quarter ended July 31, 2003 ("September 15 Form 10-Q").

95. The September 15 Form 10-Q was signed by defendant Moore, who certified that it did not "contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." Defendants Moore and Kober substantially participated in drafting, reviewing and/or approving, and defendant Richman reviewed, the non-financial reporting sections of the September 15 Form 10-Q.

96. In the September 15 Form 10-Q, Biopure did not state that the July 30 letter it had received from the FDA was a complete response letter. In addition, Biopure made the following

statement, among others:

> We Cannot Expand Indications for Our Products Unless We Receive FDA Approval for Each Proposed Indication
>
> The FDA requires a separate approval for each proposed indication for the use of Hemopure in the United States. We have applied for an indication for Hemopure that will only involve its perioperative use in patients undergoing orthopedic surgery. Subsequently, we expect to expand Hemopure's indications. To do so, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully . . . .
>
> * * *
>
> We also plan to develop Hemopure for potential use in trauma and other medical applications.

97. Biopure's September 15 Form 10-Q was false and misleading because it misled investors about the true information that the company had received from the FDA. For example, Biopure's September 15 Form 10-Q failed to disclose, among other things, that the July 30 letter from the FDA was a complete response letter. The September 15 Form 10-Q was further false and misleading because it failed to disclose that the FDA had barred Biopure from conducting clinical trials of Hemopure on trauma victims for safety reasons. The September 15 Form 10-Q further misled investors by falsely stating that an indication involving Hemopure's perioperative use in orthopedic surgery was the "only" indication applied for, when, in truth, Biopure had also sought permission to conduct trials for the trauma indication. The September 15 Form 10-Q further misled investors by disclosing a future "expectation" to expand Hemopure's indications, design additional trials and submit them to the FDA for review, when, in truth, Biopure already had designed additional clinical trials, submitted the trial designs to the FDA for review, and received a clinical hold from the FDA. The September 10 Form 10-Q further misled investors by

referring to development plans for the trauma indication without disclosing that the FDA placed the trauma indication on clinical hold for safety reasons arising out of the same data submitted in support of Biopure's BLA.

98. On October 30, 2003, Biopure issued another press release ("October 30 Press Release") and included the text of the release in a Form 8-K filed with the Commission ("October 30 Form 8-K"). Defendants Moore and Kober each substantially participated in drafting, reviewing and/or approving the October 30 Press Release.

99. The October 30 Press Release announced that defendant Richman, who had been terminated, had left Biopure. The October 30 Press Release further stated, among other things:

> Biopure Corporation (Nasdaq: BPUR) today announced its plan to respond by June 30, 2004, to the Food and Drug Administration's (FDA) questions regarding its biologic license application (BLA) for Hemopure(R) [hemoglobin glutamer - 250 (bovine)]. The company has adjusted its operating plan to reduce expenses and conserve cash while it completes its written response to the FDA.
>
> Biopure applied for FDA approval to market the company's oxygen therapeutic, Hemopure, in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.
>
> During the past two months the company has had several substantive interactions with the FDA to clarify the Agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.
>
> * * *
>
> "In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions," said Biopure President and CEO Thomas A. Moore. "We view the Agency's questions

> as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible."

100. The October 30 Press Release was false and misleading because it misled investors about the true status of Biopure's continued efforts to seek FDA approval for Hemopure. For example, in the October 30 Press Release, defendants continued to conceal from investors that the July 30 letter was a complete response letter. The October 30 Press Release was further misleading to investors because Biopure failed to disclose to investors that the June 30, 2004 planned response date was dependent upon Biopure pursuing a much narrower indication than in the original BLA. Indeed, prior to issuance of the October 30 Press Release, Biopure ignored advice from the company's outside counsel, who after reviewing a draft of the release recommended that company disclose that, "[i]n its planned response to FDA, Biopure intends to narrow its focus and seek approval only for anemia in those surgical settings where blood transfusion is not an option." The October 30 Press Release was further misleading to investors because the clinical hold on the trauma IND remained undisclosed.

101. Even though the October 30 Press Release misled investors by containing false statements and failing to disclose material facts, the market reacted to the negative -- albeit incomplete -- news that was contained in the release, including that defendant Richman had left the company and that it would take eight additional months to response to the complete response letter. On October 30, 2003, on heavy trading volume, Biopure's stock price closed at $3.68, a 39% decrease from the prior day's closing price of $6.05.

**Biopure Discloses the Complete Response Letter and the Clinical Hold**

102. On or about December 11, 2003, Biopure issued a press release ("December 11 Press Release") announcing its financial results for the fiscal year ending October 31, 2003 and included the text of the release in a Form 8-K filed with the Commission ("December 11 Form 8-K"). In the December 11 Press Release, Biopure disclosed for the first time -- and more than four months after it was issued -- that the July 30 letter from the FDA was a complete response letter. The December 11 Press Release, however, did not disclose the clinical hold on the trauma trials.

103. Defendants Moore, Richman, and Kober each substantially participated in drafting, reviewing and/or approving the December 11 Press Release.

104. On Christmas Eve, December 24, 2003, after the close of the stock markets, Biopure issued a press release ("December 24 Press Release") and included the text of the release on a Form 8-K filed with the Commission ("December 24 Form 8-K"). In the December 24, 2003 Press Release, Biopure publicly revealed for the first time the trauma clinical hold imposed by the FDA more than eight months earlier. Biopure also disclosed that the company had received a "Wells Notice" that the Commission staff had made a preliminary determination to recommend filing a civil injunctive action against the company. On the next trading day, December 26, 2003, Biopure's stock price closed down 13.83% at $2.43. On Monday, December 29, 2003, the first trading day after the Christmas holiday weekend, Biopure's stock closed at $2.33, which represented a 17.38% decrease from the closing price on December 24, 2003.

**Biopure Raised a Significant Amount of Capital from Investors**

105. While defendants were engaged in the fraudulent scheme described herein, Biopure raised a significant amount of capital in connection with the several offerings of stock during the relevant period. For example, on April 16, 2003, Biopure realized $3,032,000 in net proceeds from sale of shares and warrants. On May 2, 2003 and May 6, 2003, Biopure realized $3,134,000 and $2,935,000, respectively, in net proceeds from sales of shares and warrants. On July 23, 2003, Biopure realized $16,138,000 in net proceeds from the sale of 3,083,000 shares of common stock. Biopure also had sales of $10,000,000 of common stock issued from time to time through the standby equity distribution agreement with CMI. Biopure also received $3.2 million in net proceeds from the exercise of warrants to purchase 712,141 shares of its common stock at an average exercise price of $4.52 per share during the fiscal year ended October 31, 2003.

**Remedies**

106. The violations set forth in this Complaint involve fraud, deceit, manipulation, or deliberate or reckless disregard of a regulatory requirement and such violations directly or indirectly resulted in substantial losses or created a significant risk of substantial losses to other persons.

**FIRST CLAIM**

(Violation of Exchange Act Section 10(b) and
Exchange Act Rule 10b-5 Against All Defendants)

107. The Commission repeats and incorporates by reference the allegations in paragraphs 1-106 of the Complaint as if set forth fully herein.

108. As set forth more fully herein, each of defendants, directly or indirectly, by use of the means or instruments of interstate commerce, or of the mails, or of a facility of a national securities exchange, knowingly or recklessly (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (c) engaged in acts, transactions, practices, and courses of business which operated or would operate as a fraud or deceit upon the purchasers of securities and upon other persons, in connection with the purchase or sale of a security.

109. In connection with the acts and omissions described herein, each of defendants, acted knowingly or recklessly. Each knew, or was reckless in not knowing, that one of more of the April Offering Documents, May Prospectus Supplements, May 14 Form 8-K, May 22 Form 8-K, June 16 Form 10-Q, Summer 2003 Shelf Registration, July 3 Prospectus, July 18 Offering Document, July 17 Form 8-K, August 1 Form 8-K, August Secondary Offering Documents, September 15 Form 8-K, September 15 Prospectus, September 15 Form 10-Q, and October 30 Form 8-K (collectively, "Biopure's SEC Filings") and May 22 Press Release, May 22 Investor Call, May 30 Press Release, May 30 Investor Call, August 1 Press Release, August 21 Press Release, August 21 Investor Call, October 30 Press Release, and December 11 Press Release (collectively, "Biopure's Public Statements") employed devices, schemes and artifices to defraud, contained material misstatements and omissions, or operated or would operate as a fraud or deceit in connection with the purchasers or sale of a security.

110. By reason of the foregoing, each of defendants violated Section 10(b) of the Exchange Act and Exchange Act Rule 10b-5.

**SECOND CLAIM**

(Violation of Securities Act Section 17(a) Against All Defendants)

111. The Commission repeats and incorporates by reference the allegations in paragraphs 1-106 of the Complaint as if set forth fully herein.

112. As set forth more fully herein, each of defendants in the offer or sale of securities, by the use of means or instruments of transportation or communication in interstate commerce, or by the use of the mails, directly or indirectly: (a) employed devices, schemes or artifices to defraud; (b) obtained money or property by means of untrue statements of material facts or omissions to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in transactions, practices or courses of business which operated or would operate as a fraud or deceit upon purchasers of securities.

113. In connection with the acts and omissions described herein, each of defendants acted knowingly, recklessly, or negligently. Each knew, or was reckless in not knowing, or should have known, that one or more of Biopure's SEC Filings and Biopure's Public Statements employed devices, schemes or artifices to defraud, contained material misstatements and omissions, or operated or would operate as a fraud or deceit upon purchasers of securities.

114. By reason of the foregoing, each of defendants violated Section 17(a) of the Securities Act.

**THIRD CLAIM**

(Violation of Exchange Act Section 13(a) and
Exchange Act Rules 12b-20, 13a-11 and 13a-13 Against Defendant Biopure)

115. The Commission repeats and incorporates by reference the allegations in paragraphs 1-106 of the Complaint as if set forth fully herein.

116. Section 13(a) of the Exchange Act and Rules 13a-11 and 13a-13 thereunder require issuers of registered securities to file with the Commission factually accurate current and quarterly reports. Exchange Act Rule 12b-20 provides that in addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

117. As a result of the conduct set forth herein, Biopure violated Section 13(a) of the Exchange Act and Rules 12b-20, 13a-11 and 13a-13 thereunder.

**FOURTH CLAIM**

(Aiding and Abetting Biopure's Violations of
Exchange Act Section 13(a) and Exchange Act Rules 12b-20, 13a-11 and 13a-13
Against Defendants Moore, Richman, and Kober)

118. The Commission repeats and incorporates by reference the allegations in paragraphs 1-106 of the Complaint as if set forth fully herein.

119. Section 13(a) of the Exchange Act and Rules 13a-11 and 13a-13 thereunder require issuers of registered securities to file with the Commission factually accurate current and quarterly reports. Exchange Act Rule 12b-20 provides that in addition to the information expressly required to be included in a statement or report, there shall be added such further

material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

120. As set forth herein, one or more of Biopure's SEC Filings fraudulently misled investors about the truth regarding Biopure's efforts to gain FDA approval of Hemopure in connection with the company's trauma IND and its BLA in violation of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-11, and 13a-13 thereunder.

121. By knowingly rendering substantial assistance to one or more of Biopure's violations, each of defendants Moore, Richman, and Kober aided and abetted Biopure's violations of Section 13(a) of the Exchange Act, and Rules 12b-20, 13a-11, and 13a-13 thereunder.

**FIFTH CLAIM**

(Violation of Exchange Act Rule 13a-14 Against Defendant Moore)

122. The Commission repeats and incorporates by reference the allegations in paragraphs 1-106 of the Complaint as if set forth fully herein.

123. Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] requires that current and periodic reports filed with the Commission do not contain untrue statements of material fact or omit to state material facts necessary to make the statements made, in light of the circumstances in which they were made, not misleading. Rule 13a-14 thereunder [17 C.F.R. 240.13a-14], requires the principal executive officer and principal financial officer of the company to sign a certification that the report does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances in which such statements were made, not misleading.

124. By reason of the foregoing, defendant Moore violated Exchange Act Rule 13a-14 [17 C.F.R. 240.13a-14] in certifying each of Biopure's June 16 Form 10-Q and September 15 Form 10-Q.

**PRAYER FOR RELIEF**

**WHEREFORE**, the Commission respectfully requests that this Court:

I.

Issue a Final Judgment of Permanent Injunction permanently restraining and enjoining each of defendants Biopure, Moore, Richman, and Kober and their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation, and each of them who receive actual notice of the Final Judgement by personal service or otherwise, from violating or aiding and abetting violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)], Sections 10(b) and 13(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78m(a)] and Rules 10b-5, 12b-20, 13a-11 and 13a-13 promulgated thereunder [17 C.F.R §§ 240.10b-5, 240.12b-20, 240.13a-11 and 240.13a-13], and, as to defendant Moore only, Rule 13a-14 thereunder [17 C.F.R. § 240.13a-14].

II.

Issue an Order requiring each of defendants Biopure, Moore, Richman, and Kober to pay a civil penalty in an appropriate amount pursuant to Section 20(d) of the Securities Act and Section 21(d)(3) [15 U.S.C. §§ 77t(d) and 78u(d)(3)].

III.

Issue an Order barring defendants Moore, Richman, and Kober from serving as officers or directors of any publicly-traded issuer pursuant to Section 20(e) of the Securities Act and Section

21(d)(2) of the Exchange Act [15 U.S.C. §§ 77t(e) and 78u(d)(2)].

IV.

Grant such other relief as this Court deems just and appropriate under the circumstances.

Respectfully submitted,

By: _____

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